UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: December 17, 2018

Subject: Efficacy Review for Per-ox, EPA Reg. No. 833-4
(DP Barcode: 448801, E-Submission: 32044)

From: Thao Pham
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Kristen Willis, Team Leader
Product Science Branch
Antimicrobials Division (7510P)
Date Signed: 12/18/2018

To: Zeno Bain, Team 33 / Terria Northern
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Alex C Fergusson, LLC
c/o: Lewis & Harrison
2461 South Clark Street, Suite 710
Arlington, VA 22202

Formulation from the Label:

Active Ingredient(s)	% by wt.
Peroxyacetic acid	5.25%
Hydrogen peroxide	22.00%
Other Ingredients	72.75%
Total	100.00%

I BACKGROUND

Product Description (as packaged, as applied): Liquid concentrate

Submission type: Label amendment

Currently registered efficacy claim(s): broad spectrum disinfectant (bactericidal), food contact surface sanitizer, and fruit and veggie surfaces

Requested action(s): Adding food contact sanitizer by fogging claim and new label directions for foam cleaning and nonpublic health claims.

Documents considered in this review:

- Letter from applicant to EPA dated August 31, 2018
- Data Matrix (EPA Form 8570-35), dated September 21, 2018
- 1 efficacy study (MRID 50668501)
- Proposed label dated August 31, 2018

II PROPOSED DIRECTIONS FOR USE

"**For Use in Dairies, Beverage and Food-Processing Plants (including meat and poultry processing plants)**
Use this product to control the growth of non-public health microorganisms that can cause decay and/or spoilage and as a sanitizer against *Staphylococcus aureus* and *Escherichia coli*.
Prior to fogging, remove food products and packaging material from the room or area to be treated or carefully protect. Fog desired area with 2.0 fl. oz. of Per-Ox per 5 gallons of water per 1000 cubic feet of room area. Wear a dust mist respirator when preparing the use-solution and pouring it into the fogging apparatus. Vacate the area of all personnel during fogging and for at least 2 hours after fogging is completed. Only use in areas that have a minimum of 4 air exchanges (ACH) per hour. If the treatment area must be entered prior to 2 hours, then the individuals entering the area must wear a self-contained respirator approved by NIOSH/MSHA, googles, long sleeves, and long pants."

III STUDY SUMMARIES

1.	**MRID**	506685-01	**Study Completion Date:**		5/19/17		
Study Objective		Sanitizer/Fogger					
Testing Lab; Lab Study ID		Accuratus Lab Services; A23110					
Test organism(s) **☐ 1 ☒ 2 ☐ 3 ☐ 4+**		*Staphylococcus aureus* (ATCC 6538) and *Escherichia coli* (ATCC 11229)					
Test Method		Efficacy of a Sanitizer Applied to a Room via a Fogging, Misting, or Vaporizing Device for Food Contact Sanitization (Protocol # AFC01022117.FCRST)					
Application Method		Lafferty 633 4-Way Fogger					
Test Substance Preparation	**Name/ID**	PER-OX					
	Lots **☐ 1 ☐ 2 ☒ 3**	6000, 6001, 6002					
	Preparation	Tested concentration: LCL Dilution: 0.40 oz/gallon Diluent: Sterile deionized water					
Soil load		No soil load					
Carrier type, # per lot		3"x3" glass slides, 20					
Test conditions		**Contact time**	15 mins	**Temp**	21.6-23.1°C	**RH**	48.0-61.3%
Neutralizer		Letheen Broth + 0.1% Sodium Thiosulfate + 0.01% Catalase					
Reviewer comments		A single carrier was placed in each of the twenty designated					

(i.e. protocol deviations and amendments, retesting, control failures, etc.)	locations, designed to evaluate the following areas of the room: 1. All corners 2. Central locations on all wall faces 3. Central locations on the floor 4. Multiple locations and heights within the enclosed space 5. Underneath horizontal surfaces Each carrier was oriented horizontally with the inoculum facing up in the petri dish. The air compressor was placed in the middle of the room and allowed to build up to 125 – 130 psi. Total cycle time was 32-35 minutes (15-minute exposure time plus aeration time). The active ingredient concentration was monitored using PAA test strips placed at different locations. All test strip results indicated exposure to a minimum concentration of 100 ppm peracetic acid.

IV STUDY RESULTS

Disinfection – Bactericidal Efficacy

MRID (Test Date)	Organism	Log_{10} Reduction			Average log_{10} CFU/Carrier
		Batch 6000	Batch 6001	Batch 6002	
15-minute contact time, sterile deionized water, no soil load, 0.40 oz/gallon					
50668501 (5/4/17)	*Staphylococcus aureus* (ATCC 6538)	>6.48	-	-	6.48
(5/4/17)		-	>6.41	-	6.41
(5/5/17)		-	-	>6.42	6.42
(5/4/17)	*Escherichia coli* (ATCC 11229)	>7.35	-	-	7.35
(5/4/17)		-	>7.42	-	7.42
(5/5/17)		-	-	>7.32	7.32

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50668501	Sanitizer, bactericidal	Hard, non-porous surfaces	Fogger, 0.40 fl. oz. per gallon	15 minutes	No soil load	Sterile deionized water	• *Staphylococcus aureus* (ATCC 6538) • *Escherichia coli* (ATCC 11229)	**Yes**

VI LABEL COMMENTS

Label Date: 8-31-2018

1. The proposed label claims that the product, Per-ox, when diluted at 2 fl oz. per 5 gallons of water, is an effective fogging sanitizer against the following on hard, non-porous surfaces:

   Staphylococcus aureus (ATCC 6538)
   Escherichia coli (ATCC 11229)

   These claims are **partially acceptable**. Revise use instructions on page 5 of the label to include the following:
   - clearly state that surfaces to be treated should be precleaned.
   - sterile deionized water should be used to dilute the product.
   - specify a minimum 15-minute contact time and pressure of 125-130 psi.
   - include directions for monitoring of the active ingredient to ensure the minimum effective dose has been achieved as well as the re-entry level concentration.
   - revise the room size to reflect the room size tested (104 m^3 or 238 ft^2).
   - provide information about the type of fogging apparatus to be used to reflect the fogging apparatus that was tested (Lafferty Portable 633 fogger) and reference that the instructions for use for that apparatus should be followed.

2. Make the following changes to the proposed label:
   a. As testing was conducted using sterile deionized water as the diluent, all use directions throughout the label should clearly specify dilution with sterile deionized water in place of "potable water".

   b. On page 1 of the proposed label, clearly indicate that "institutional" does not include hospital and healthcare facilities.

   c. On page 2 of the label, instructions for sanitizing at lower than room temperature must be removed unless supported by efficacy data. Current data matrix does not support this claim.

   d. On pages 2 and 3 of the label, revise "*Salmonella typhimurium*" to "*Salmonella enterica*" to reflect the change in designation by ATCC.

   e. On page 4 of the label,
      (i) remove claims against *Aspergillus versicolor* as this organism is potentially pathogenic and should be supported with efficacy data.
      (ii) instructions for treatment of raw fruit and vegetable surfaces and processing water should also include instructions for precleaning to help reduce cross-contamination.

   f. On page 5 of the label, revise the directions for use for "Foam Cleaning of Food and Non-Food Contact Surfaces" section to omit mention of sanitizing or sanitizer/disinfectant as it may be misleading ot the user.

   g. Note to PM: Please check list of raw commodities on page 4 against the CFR.